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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,567	07/20/2001	Roberto A. Macina	DEX-0214	4354

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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	13

DATE MAILED: 10/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/909,567	Applicant(s) MACINA ET AL.	
	Examiner Carolyn L Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 3-16 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-2 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 and 12 (3 sheets).
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group I (claims 1-2), a specie election of polynucleotide, and a sequence election of SEQ ID NO: 12 within the restriction of Group I in Paper No. 11, filed August 27, 2002, is acknowledged. The applicant's traversal is on the grounds that there is insufficient support for limiting the number of nucleic acid sequences to one sequence, to requiring a species election, or separating the claims into nine inventions.

The traversal to limiting the number of nucleic acid sequences to one was found unpersuasive because, due to the number of these requests made, it is practically impossible to accommodate all requests. The overwhelming number of sequences poses undue search burden when more than one nucleic acid sequence is elected, thus making the previous waiver to a complete search of all 24 sequences, effectively impossible to reasonably implement.

The applicant's request to withdraw the species election requirement was found unpersuasive because of the following reasons (reiterated from the restriction paper):

All claims in Groups I-IV, VII, and IX are generic to the polynucleotide and polypeptide species which are distinct or independent due to the fact that they are directed to different chemical types regarding the critical limitations therein. For the polynucleotide species, the critical feature is a polynucleotide. For the polypeptide species, the critical feature is a polypeptide. These species have been most commonly, albeit not always, separately characterized and published in biochemical literature. Also, it is pointed out that processing that may connect two Groups does not prevent them from

being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

The applicant's request to withdraw the restriction of the nine separate inventions into one was found unpersuasive because of the following reasons (summarized from the restriction paper):

The inventions are distinct when they are directed to different chemical types (see pp. 6-7, Election/Restriction Requirement in Paper No. 10). The invention Groupings that are related as product and processes of use (see pp. 7-9, Election/Restriction Requirement in Paper No. 10), can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. Also, please note the different classes and subclasses under which the examiner has classified each Group. This lack of overlapping searches documents the undue search burden if they were searched together. The requirements are still deemed proper and are therefore made FINAL.

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to compositions and methods whereas in contrast the elected claims include only compositions.

Claims herein under examination are claims 1 and 2.

PATENTABLE UTILITY GUIDELINES

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1 and 2 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The critical limitation of claims 1 and 2 is the nucleotide sequence of the claimed polynucleotide SEQ ID NO: 12. While some data are supplied for several sequences, such as for SEQ ID NO: 1 on pages 97-99, no data therein indicate any specificity regarding the elected SEQ ID NO: 12. The claimed nucleic acid is not supported by a specific asserted utility because the other disclosed uses (not specified for any particular sequence) mentioned in the specification are generally applicable to many nucleic acids. The specification states that the polynucleotide sequences may be useful in "identifying, diagnosing, monitoring, staging, imaging, and treating lung cancer and non-cancerous disease states in lung, identifying lung tissue, monitoring and modifying lung embryonic development and differentiation, and identifying and/or designing agonists and antagonists of polypeptides" as well as "gene therapy, production of transgenic animals and cells, and production of engineered lung tissue for treatment and research" (p. 1, lines 20-28). In fact, the specification summarized modern biotechnology generally but never connects the specifically elected sequence (SEQ ID NO: 12) to any particular or available utility. The above-mentioned list of desirable utility for the claimed sequence falls short of a readily available utility. These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the polynucleotide being claimed.

Further, the claimed polynucleotide is not supported by a substantial utility because is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, the protein produced as a final product resulting from processes involving the nucleic acid does not have asserted or identified specific and substantial utilities. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved, such as the LSG encoded by SEQ ID NO: 12, does not define a "real world" context for use. Similarly, the other listed utilities and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to many such compounds.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claims Rejected Under U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF ENABLEMENT

Claims 1 and 2 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed sequence. For a sequence putatively assigned a biological function, even if correct, does not appear to be defined as to what use it is to be applied to. The significance of the sequence is undefined, further rendering it indiscernible how someone of skill in the art would use such an entity.

Due to the large quantity of experimentation necessary to determine activity or property of the disclosed nucleic acid such that it can be determined how to use the claimed sequence, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, and the breadth of the claims which fail to recite particular biological activities, the specification fails to teach the skilled artisan how to make and use the claimed invention.

Also, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above (refer to 35 U.S.C. § 101 rejection), one skilled in the art would not know how to use the claimed invention.

LACK OF WRITTEN DESCRIPTION

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 12 which corresponds to DNA encoding an LSG (lung specific gene). Claims 1 and 2 are directed to encompass gene sequences, sequences that hybridize to the antisense sequence of SEQ ID NO: 12, and variants. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 12, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only SEQ ID NO: 12 but not the full breadth of the claims 1 and 2 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Regarding claims 1 and 2, the claims contain embodiments which are beyond the elected invention. Correction is suggested by stating only the embodiments which are part of the invention.

Regarding claims 1 and 2, the claims are vague and indefinite due to the unclarity of citing the abbreviation LSG. Correction is suggested by amending in of the full name in parentheses.

Regarding claims 1 and 2, the claims are vague and indefinite due to the unclarity of the phrase "or a variant thereof." The claims do not adequately define the phrase which could mean a variant which is 5% different and of the same length as the claimed polynucleotide or 20% different and only a fragment of the sequence or any other

scenario. Appropriate definition regarding the degree of variation to the claimed polynucleotide is required.

Regarding claims 1 and 2, claim 1 recites the phrase "polynucleotide which is capable of hybridizing under stringent conditions" which is vague and indefinite. It is unclear which criteria the applicants regard as stringent conditions (i.e. buffers, pH of buffer, etc.) or whether low, medium, or high stringency is meant. Applicants can resolve this issue by particularly pointing out the stringent conditions that are intended to allow the polynucleotide to hybridize. Clarification of the metes and bounds of the instant claims is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigma (1990). Sigma Catalog includes O 3003 (oligothymidylic acid, $d[pT]_4$), which is an oligomer that matches a segment of SEQ ID NO: 12 (nucleotide positions 575-578). Claim 1 indicates in line 2 "a polynucleotide of…" which supports the concept that subsequences such as short oligomers are included. Thus, the 1990 Sigma Catalog teaches one of the limitation choices in claim 1.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bandman et al. (2001). As the "variant" was undefined (regarding the variation in nucleotides or sequence length), Bandman et al. disclosed a sequence (SEQ ID NO: 16) which contains an identical matching polynucleotide sequence (nucleotide positions 79-705, col. 75-78) to a fragment of SEQ ID NO: 12 (nucleotide positions 612-1237) of the instant claims. Bandman et al. disclosed SEQ ID NO: 16 (col. 75-78) encodes a protein of SEQ ID NO: 4 (col. 49-52, col. 14, lines 25-33). Bandman et al. disclosed a polynucleotide sequence which hybridizes under stringent conditions to the polynucleotide encoding the polypeptide of SEQ ID NO: 4 (col. 4, lines 46-51), a sequence which is complementary to the polynucleotide encoding the polypeptide of SEQ ID NO: 4 (col. 4, lines 55-59), and hybridizing the complement of the polynucleotide encoding SEQ ID NO: 4 to a polynucleotide encoding HUPM (i.e. SEQ ID NO:16) (col. 4, lines 9-15 and col. 6, lines 11-20). Thus, Bandman et al. teaches all of the limitations in claims 1 and 2.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 9 A.M. to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 27, 2002

ARDIN H. MARSCHEL
PRIMARY EXAMINER